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APPLICATION NUMBER	FILED DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

20
9/24/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/14/97

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 6-10, 12, 14, 16-30 is/are pending in the application.
Of the above, claim(s) 6-10, 12, 14, 16-20 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1, 21-30 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1, 6-10, 12, 14, 16-30 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

Part III: Detailed Office Action

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.129(a). Applicant's second submission after final filed on 7/14/97 has been entered.

Claims 1 and 21-30 are under consideration.

Formal Matters:

The amendment to the brief description figure 9 is acknowledged.

Double Patenting Rejections:

Claims 1 and 21-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 5,010,010 for reasons of record in paper number 15, mailed 5/28/96, at page 5.

Applicants intention to overcome this rejection by submission of a terminal disclaimer is noted.

Objections and Rejections under 35 U.S.C. §112:

Claims 27 and 28 remain, and newly submitted claims 29 and 30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 27, the metes and bounds of "fully active in an adenylate cyclase assay" are not clear; while a protein is described in the specification as being "fully active in an adenylate cyclase assay", the specification does not give any indication of what "full activity" is. Therefore, the metes and bounds of claims 27 and 28 are not clear.

Applicants argument that the term in question would be understood by those of ordinary skill

in the art as meaning that the "recombinant protein is as active in this particular type of assay as would be predicted for a pure protein of this type" has been fully considered but is not deemed persuasive, for reasons of record. Specifically, it remains that "full activity" is a relative term, and would depend upon the specific assay used, the conditions under which it were performed, and to what the sample was being compared. Therefore, the term remains indefinite, as none of these parameters have been specified.

Claims 29 and 30 are indefinite for using the term "intact". As set forth in paper number 15, the metes and bounds of the newly introduced term "intact" are not clear. It is noted that the common usage of the term is to refer to something that is whole (e.g. not degraded), however alternative meanings include "not damaged in any way" (Webster's II New Riverside University Dictionary). It is not clear in what sense applicants intend the term, nor, if the latter definition is included, what constitutes "damaged". In the two declarations under 37 C.F.R. §1.132 (submitted with paper number 13, filed 3/8/96), it would appear that declarants are urging that the term excludes any *variant* of hPTH; however, such limitation cannot be imputed. Claim 29 is further indefinite for reciting a "maximal response", as it is not clear to *what* the response is generated; such might be an immune response when injected into an animal, or alternatively might indicate some unspecified physiological response to the hormone. Finally, the claim is indefinite because it is drawn to a pure hormone, but concludes with a purification step in the active voice; the claim should be amended to recite either "obtained by *expressing*...and purifying", or alternatively "obtained by expression... and *purification*", e. g. to use consistently either the active or the passive voice, to be remedial for this particular point.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country

or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

5 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in
10 which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same
15 person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and
20 invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1 and 21-30 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Brewer et al., U.S. Patent Number 3,886,132 for
25 reasons cited in the Office Action, paper number 8 mailed 9/8/95, at page(s)5-7.

Applicants arguments filed 7/14/97 have been fully considered but are not deemed persuasive. Applicants argue at pages 3-4 that the Examiner is holding an inconsistent position, having cited an art-recognized motivation to make proteins recombinantly in a copending case, while maintaining that the product of such a process is patentably indistinct from the purified, naturally occurring protein.
30 The Examiner does not agree that this position is inconsistent, and in fact, this position is supported by the case law. When claimed product and prior art product reasonably appear to be the same, the

burden of proof is on Applicant to demonstrate a novel or unobvious difference between the claimed product and that of the prior art; See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923. See also the previous Office Action, paper number 18, at page 5. Thus, although it may have been obvious to make the protein via recombinant means, it remains that the product of that process has not been shown to be patentably distinct from the purified naturally occurring protein. Far from being inconsistent, the Examiner notes that it is *because* an indistinguishable protein may be made by recombinant means in many cases that such recombinant production is useful. The recombinantly made protein is expected to retain the biological activity of the naturally occurring; the advantage of the recombinant production is ease of purification, etc., none of which necessarily impart distinctness to the resulting protein itself. Applicants arguments of the *Brewer* reference have been fully addressed previously; see the previous Office Action, paper number 18, at page 6. Contrary to applicants assertion, there has been no demonstration of any unexpected result in this case with respect to the purity or activity of the recombinantly produced protein. Although the claimed protein might, in *arguendo*, be superior to chemically synthesized protein, it remains, as evidenced by pending claims, e.g. claims 21 and 30, that the claimed product is equivalent in all disclosed respects to the protein as purified from its natural source.

Advisory Information:

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 8:00 A.M. to 4:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Stephen Walsh, can be reached at (703)308-2957.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

5 Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

10 Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

15 Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [stephen.walsh@uspto.gov].

20 All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

25

30 Lorraine Spector, Ph.D.
Patent Examiner

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Lorraine Spector, Ph.D.
Patent Examiner

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